DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0056]

2-23-05
2-24-05

Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated November 2004. The guidance document provides medical device manufacturers with information about performing studies to support modifying the indication for use of communicable disease tests to include testing of cadaveric blood specimens to screen donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The guidance document recommends a suggested protocol to modify the indication for use to include testing of cadaveric blood specimens.

DATES: Submit written or electronic comments on agency guidances at any time. In accordance with 21 CFR 10.115(g)(4)(i), FDA is immediately implementing this guidance.

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ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated November 2004. The guidance document provides information to medical device manufacturers of communicable disease tests used to screen donors of HCT/Ps for communicable diseases who plan to perform studies to validate the use of cadaveric blood specimens with their tests. The guidance

supercedes the May 2, 1995, letter issued by FDA to manufacturers of communicable disease tests suggesting a minimum protocol for validation of use of cadaveric blood specimens with their donor screening tests.

The guidance recommends a minimum suggested protocol to validate an indication for use of cadaveric blood specimens with communicable disease tests used to screen donors of HCT/Ps. The guidance makes recommendations about: (1) Sensitivity and specificity studies, (2) reproducibility studies, (3) number of test kit lots to include in studies, (4) plasma dilution issues, and (5) information about specimen collection times to be included.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

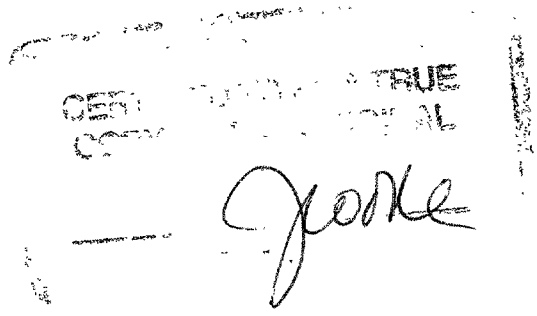
III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 2/16/05

February 16, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.



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